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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,077

Applicant(s)

Fleckenstein et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 3, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) 5-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Claims 1-29 are pending.

Response to restriction requirement filed 3/3/03 is acknowledged. Applicant elected Group I, claims 1-5,11, with traverse regarding Groups I and II. Polypeptides of Group I, and polynucleotides of Group II are independent and/or patentably distinct compounds since each of these compounds possess different structure (e.g.,primary, secondary and tertiary structure) and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Each of the claimed inventions are differently classified and each sequence, whether a polypeptide or polynucleotide, requires further searching and consideration. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 6-10,12-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

In regard to election of species requirement, applicant elected SEQ ID No. 3 in unmodified form. Claims 5, 11 are withdrawn from consideration as drawn to non-elected species.

Claims 1-4 are under consideration to the extent they read on the elected species.

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Specification

2. The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, pages 16, line 9. Applicant is requested to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(b).

Information Disclosure Statement

3. Applicants' Information Disclosure Statement filed 4/16/01 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Sequence Listing

4. The Sequence Listing was approved by STIC for matters of form.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 1: The claims vague and indefinite because it recites four different domains, none of which is structurally defined. It is not clear what, structurally, constitutes 1) N-terminal peptide; 2) Sema domain; 3) C-terminal domain, and its components (3a) immunoglobulin-like domain, and (3b) transmembrane domain. Without further clarification the claim reads on any transmembrane protein.

B. Claim 1: further, it is not clear what defines an "immunoiglobulin-like domain". The metes and bounds of the term are not clear.

C. Claim 2: The term "corresponds to SEQ ID No. 3" is vague and unclear. The term "corresponds " is not defined by the claim. It is unclear how one sequence can correspond to another; does it mean that sequences are identical, homologous?

C. Claim 3: As in claim 1, it is not clear what constitutes a Sema domain of the claimed protein. Further, as it is not clear what is Sema domain in protein SEQ ID No. 3, the structure of the claimed protein which has >40% homology to Sema domain in protein SEQ ID No. 3 is also vague and indefinite.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID No. 3, which corresponds to human species of semaphorin protein. Protein SEQ ID No. 3 meets the provision of written description. However, the claims are also drawn to proteins having as little as 15-20 % identity to SEQ ID No. 3 (claim 4) or have 40% homology to Sema domain in protein SEQ ID No. 3 (claim 3), or, in general, have structurally unidentified sequences having a N-terminal sequence, Sema domain, and C-terminal domain (claim 1). As such, the claims encompass sequences from other species, mutated sequences, allelic variants, splice variants, etc. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support genus encompassed by the claims. The various structural characteristics, such as N-terminal peptide, Sema domain, immunoglobulin-like domain, and transmembrane domain are not so clearly defined

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as in the art that one of skill in art would immediately be appraised of the members of the genus of proteins. A transmembrane domain can vary in structure and sequence from a single membrane-spanning domain to a domain that spans the membrane in several places and in an unusual configurations, like a G-protein coupled receptor. Such structures can not necessarily be predicted by sequence homology or by naming a sequence motif. In the case of immunoglobulin-like domain, it is not clear what activities or structures of the immunoglobulin must be "immunoglobulin-like". The antigen-binding region? The Fc portion? Or does applicant refers to a type of three-dimensional folding characteristics of an immunoglobulin domain. Further, the Sema domain does not appear to be clearly defined so a sufficient homology to this domain is difficult to visualize. The sequences disclosed in the specification do not allow for speculations regarding these questions, nor do they disclose a representative number of species sufficient to demonstrate that applicant was in possession of the claimed invention at the time of filing.

Further, the proteins with the degree of homology claimed encompass proteins unrelated to semaphorins. For example, a protein described in WO 01/77137 has the claimed degree of homology (see attached sequence alignment); yet, it is a fusion protein of factor X and albumin, i.e., unrelated to semaphorin. Similarly, Raper et al.

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(US Patent 5416197) teaches protein collapsing having the claimed degree of homology (see attached sequence alignment) but unrelated to semaphorin.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

In the instant case, the only products disclosed in the specification is the protein SEQ ID No. 3. With the exception of SEQ ID No. 3, the skilled artisan can not envision the detailed chemical structure of the encompassed proteins.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371⁶ of this title before the invention thereof by the applicant for patent.

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7. Claims 1-4 are rejected under 35 U.S.C. 102(a) as anticipated by Ensser et al. (J. Virology, 1997, p. 6517-6525).

The reference teaches an isolated protein which is about 40% identical to SEQ ID No. 3 (37%, see sequence alignment attached). The homology is throughout the molecule, suggesting that each of the recited domains is present.

8. Claims 1-4 are rejected under 35 U.S.C. 102(e) as anticipated by Goodman et al (US Patents 5935865, 5807826, 5639856, 6013781, 6344544).

The referenced patents teach an isolated protein having a sequence which is derivative of SEQ ID No. 3 and is 18% identical to SEQ ID No. 3 (see sequence alignment attached). The homology is throughout the molecule, suggesting that each of the recited domains is present. Goodman discloses that the protein can be glycosylated or phosphorylated.

9. Claims 1-4 are rejected under 35 U.S.C. 102(e) as anticipated by Raper et al. (US Patent 5416197).

The referenced patent teaches human collapsing having a sequence which 15% identical to SEQ ID No. 3. This homology is throughout the molecule, suggesting that each of the instantly recited domains is present.

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10. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by Pushel et al.(Neuron, 14, 941-948, 1995).

The referenced patent teaches murine semaphorin having a sequence which is 17% identical to SEQ ID No. 3. This homology is throughout the molecule, suggesting that each of the instantly recited domains is present.

Conclusion.

11. No claims are allowed

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 8, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

